



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/527,133                       | 03/08/2005  | Francesco Sias       | 4462-13             | 9432             |
| 23117                            | 7590        | 12/24/2008           | EXAMINER            |                  |
| NIXON & VANDERHYE, PC            |             |                      | NIA, ALIREZA        |                  |
| 901 NORTH GLEBE ROAD, 11TH FLOOR |             |                      |                     |                  |
| ARLINGTON, VA 22203              |             |                      | ART UNIT            | PAPER NUMBER     |
|                                  |             |                      | 3739                |                  |
|                                  |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                  |             |                      | 12/24/2008          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/527,133             | SIAS, FRANCESCO     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | ALIREZA NIA            | 3739                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 December 2008.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 25-35,37-48 and 50-56 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 25-35,37-47 and 50-56 is/are rejected.  
 7) Claim(s) 48 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 12 June 2008 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action mailed December 4<sup>th</sup>, 2008 is persuasive and, therefore, the finality of that action is withdrawn.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaji 6,142,931.**

4. Kaji discloses an anoscope 1, comprising a first hollow body 3 open at opposite ends A,B and a second hollow body 4 open at opposite ends C,D (see inserted image 1 below) shapingly coupled with said first hollow body 3 and arranged to coaxially rotate inside said first hollow body 3, said second hollow body 4 being provided with a window 32 arranged to make a portion of rectal mucous membrane accessible via 31, wherein said window 32 comprises an operating window 32 and has dimensions and a shape such as to enable a surgical device 38 to intervene on said portion, wherein the operating window 32 is of constant size (the size of the window 32 does not change). Kaji further discloses an angular positioning element 6,9 arranged to adjust the relative angular position 54 of said second hollow body 4 in said first hollow body 3 in preset reciprocal angular positions 54.

**5. Claims 25-29, 32-35, 37, 38, 50, 53-54, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Longo 6,142,933.**

6. With respect to claims 25-26, 34-35, 37, 38, 50, 52-53, and 56, Longo discloses an anoscope 100,120 (fig. 1), comprising a first hollow body 101 open at opposite ends 104,106 and a second hollow body 120 open at opposite ends A,B shapingly coupled with said first hollow body 101 and arranged to coaxially rotate inside said first hollow body 101, said second hollow body 120 being provided with a window 123 arranged to make a portion 91 of rectal mucous membrane accessible (fig. 9), wherein said window 123 comprises an operating window 123 and has dimensions and a shape as to enable a surgical device 29 to intervene on said portion 91, wherein the operating window 123 is of constant size (col. 5, lines 42-55, col. 6, lines 8-19, col. 6, lines 38-44, col. 9, lines 1-54, figs. 1,3,9, see inserted images 2 and 3 below). Longo further discloses an angular positioning element 103,125 arranged to adjust the relative angular position of said second hollow body 120 in said first hollow body 101 in preset reciprocal angular positions via 125,126 (fig. 3), wherein said second hollow body 120 comprises a rotation segment 126 and an operating segment 105,125,128, that can be associated with one another before use via 125 (fig. 1), wherein said window 123 is arranged on said operating segment 105,125,128 via 121, wherein said operating window 123 is defined by a U-shaped cut (fig. 2), wherein said window 123 opens near to the point that can be reached by the tip of an index finger of a hand of an individual of medium build, by inserting said index finger inside said second hollow body 120 via 124 (fig. 2,9), wherein the operating window 123 is positioned beyond the distal end 106 of the first hollow body 101 (fig. 9). Longo further discloses a method for treating hemorrhoids using the anoscope 100,120 (fig. 1,9), the method comprising, orienting

a grip 125,126 of the anoscope 100,120 parallel to the intergluteal sulcus of the patient, rotating the second hollow body 120 relative to the first hollow body 101 while maintaining the first hollow body 101 in a stationary position, temporarily fixing the second hollow body 120 in one of six preset angular positions corresponding to the arterial branches of the patient's rectal wall 90, and surgically treating any hemorrhoids 90,91 at each of six preset angular positions.

Longo further discloses a convex portion E (see inserted image 2 below) of the U-shaped operating window 123 oriented towards the first hollow body 101, and an open end B of the U-shaped operating window 123 is arranged at a distal end of the second hollow body 120 (fig. 9), wherein the operating window 123 is of constant size independent of the rotational positions of the first 101 and second 120 bodies relative to one another.

7. With respect to the methods recited in claim 52, where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

8. With respect to claims 27-29, 32-33, 51, and 54, Longo discloses an anoscope 100,120 comprising a first hollow body 101 open at opposite ends 104,106 and a second hollow body 120 open at opposite ends A,B (see inserted image 2 and 3 below) shapingly coupled with said first hollow body 101 and arranged to coaxially rotate inside said first hollow body 101, said second hollow body 120 being provided with a window 123 arranged to make a portion 91 of rectal mucous membrane accessible, wherein an angular positioning element 103,125 is provided to adjust the relative angular position of said second hollow body 120 in said first hollow body 101

in preset reciprocal angular positions via 125,126, said reciprocal angular positions corresponding to a same number of positions that can be taken up by said window 123 (360°), wherein the first 101 and second 120 hollow bodies are rotatable relative to one another while the operating window 123 maintains a constant size and allows access to the rectal mucous membrane 90 at all of said reciprocal angular positions (col. 9, lines 1-38, figs. 1,3,9), wherein said window 123 has dimensions and a shape such as to enable a surgical device 29 to intervene on said portion 90,91 (fig. 9), wherein said first hollow body 101 comprises a first truncated-cone portion 102 (fig. 1), wherein said first hollow body 101 has an edge C (see inserted image 1 below) that is comprised in a base D of said first truncated-cone portion 102, wherein said second hollow body 120 comprises a rotation segment 126 and an operating segment 125,128, that can be associated with one another before use via 125 (figs. 2, 3), wherein the preset angular positions correspond to arterial branches of a patient's rectal wall, wherein the window 123 of the second hollow body 120 is provided at a distal end B of the second hollow body 120, and the second hollow body 120 protrudes outside and beyond a distal end 106 of the first hollow body 101 (figs. 1,2,3,9).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**10. Claims 30 and 31 rejected under 35 U.S.C. 103(a) as being unpatentable over Longo 6,142,933 in view of Chikama 5,345,926.**

11. With respect to claims 30-31, Longo discloses the invention as discussed above. However, Longo fails to positively disclose said first hollow body comprises a first truncated-cone portion, wherein said first truncated-cone portion is solidly connected with a second truncated-cone portion that has a progressively decreasing cross-section, wherein said second truncated-cone portion is solidly connected with a third truncated-cone portion that protrudes from a part opposite said first truncated-cone portion and has a progressively decreasing cross-section, wherein said edge is comprised in a base of said first truncated-cone portion.

12. Chikama teaches a first hollow body A,B in an analogous medical observation instrument, said first hollow body comprising a first truncated-cone shaped portion 23, wherein said first truncated-cone portion 23 is solidly connected with a second truncated-cone portion 21C,121X that has a progressively decreasing cross-section, wherein said second truncated-cone portion 21C,121X is solidly connected with a third truncated-cone portion 22 that protrudes from a part opposite said first truncated-cone portion 23 and has a progressively decreasing cross-section (figs. 2,5), wherein said first hollow body has an edge that is comprised in a base of said first truncated-cone portion 23, resulting in an improved medical device which an observation sleeve that is disposable and in which the observation sleeve is supported in a stable manner (col. 2, lines 11-13).

13. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the anoscope of Longo with the above discussed limitations as taught by Chikama in order to have provided an improved vaginal speculum having an observation sleeve that is disposable and in which the observation sleeve is supported in a stable manner and yet can be discarded quickly after use, which guarantees reliable and safe use of the speculum while

facilitating quick and efficient turn around of an operating room after surgery has been completed.

**14. Claims 39-43 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Longo 6,142,933 in view of Boebel 4,538,594.**

15. Longo discloses the invention as discussed above. Longo further discloses said angular positioning element 103,125 is integral with said rotation segment 126 via 125 (and by coming into contact with 101).

16. However, Longo fails to positively disclose said edge comprises a plurality of notches, wherein said notches are 6 in number, wherein said notches are arranged along said edge according to the hours on an imaginary clock-face, wherein said notches are arranged at 1 o'clock, 3 o'clock, 5 o'clock, 7 o'clock, 9 o'clock, 11 o'clock. Longo also fails to positively disclose said angular positioning element comprises a plurality of teeth, wherein said plurality of teeth comprises a locking tooth, wherein said locking tooth comprises a recess housing a peg.

17. Boebel teaches notches via 2 on an edge of a first truncated-cone portion of an analogous first hollow body 1 of an anoscope 1, wherein said edge comprises a plurality of notches via 2 (fig. 1), wherein said notches are 6 in number (fig. 1), wherein said notches are arranged along said edge according to the hours on an imaginary clock-face (fig. 1), wherein said notches are arranged at 1 o'clock, 3 o'clock, 5 o'clock, 7 o'clock, 9 o'clock, 11 o'clock. Boebel further teaches a plurality of teeth 34 on a similar angular positioning element (fig. 7), wherein said plurality of teeth 34 comprises a locking tooth 33, wherein said locking teeth comprises a recess 33 housing a peg Z (see inserted image 4 below). Furthermore, Boebel teaches an elastic element 8 that can be interposed between the peg and the bottom of said recess 33, resulting in

an improved rectoscope that secures access to the rectum without surgical interventions, whilst at the same time being able to make use of all auxiliary instruments needed for intestinal surgery under observation by means of an optical system (col. 1, lines 16-20).

18. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the anoscope of Longo with the above discussed limitations as taught by Boebel in order to have provided improved rectoscope that secures access to the rectum without surgical interventions, whilst at the same time being able to make use of all auxiliary instruments needed for intestinal surgery under observation by means of an optical system, facilitating an efficient and a more effective rectum and intestinal surgery.

**19. Claims 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Longo 6,142,933 in view of Boebel 4,538,594 further in view of Golson 2,482,971.**

20. Longo in view of Boebel discloses the invention as discussed above. However, Longo in view of Boebel fails to positively disclose said angular positioning element comprises a plurality of teeth, wherein said plurality of teeth comprises a locking tooth.

21. Golson teaches an analogous anoscope having an angular positioning element 16 that comprises a plurality of teeth 16, wherein said plurality of teeth comprises a locking tooth 16 (fig. 3), resulting in a new and novel self-illuminated, transparent proctoscope adapted for use in visually examining and treating rectal abnormalities (col. 2, lines 31-45).

22. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Longo in view of Boebel with the above discussed limitations as taught by Golson in order to have provided a new and novel self-illuminated, transparent proctoscope adapted for use in visually examining and treating the lower rectal region and

whereby the entire surrounding rectal wall may be visually examined at one time without the aid of an auxiliary light.

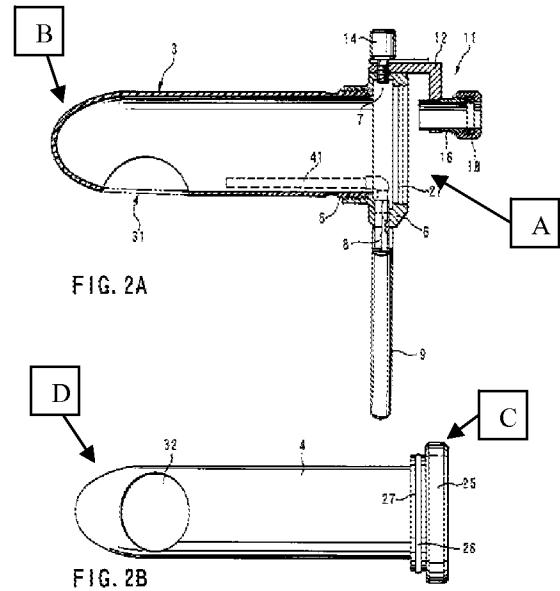
**23. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Longo 6,142,933 in view of Hamilton US 348,843.**

24. Longo discloses the invention as discussed above. However, Longo fails to positively disclose the positioning element includes a locking member that maintains alignment with the window during rotation of the second hollow body.

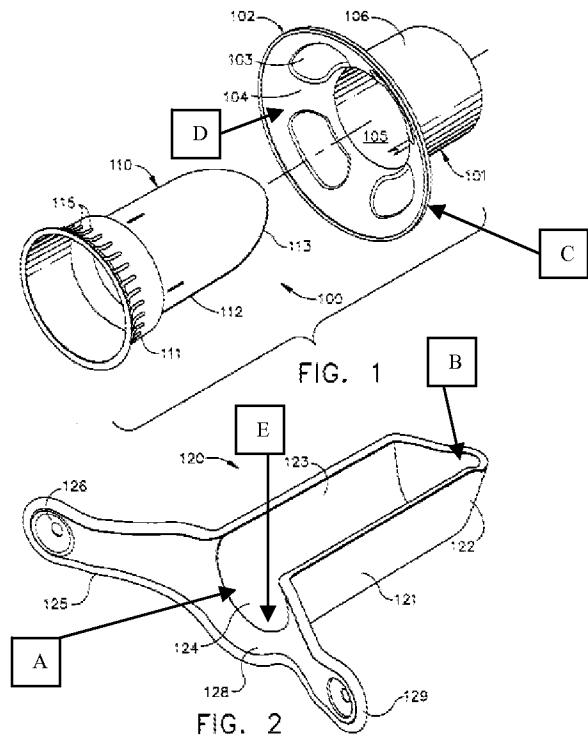
25. Hamilton teaches an analogous anoscope that comprises a positioning element c that includes a locking member c,d that maintains alignment with a window during rotation of a second hollow body c' (figs. 1,2,3, col. 2, lines 58-77), resulting in an improved rectal speculum having improvement in the construction of the case and the gate thereof, whereby greater convenience and effectiveness in locking are securing the device is ensured.

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the anoscope of Longo with the above discussed limitations as taught by Hamilton in order to have provided an improved rectal speculum having improvement in the construction of the case and the gate thereof, whereby greater convenience and effectiveness in locking are securing the device is ensured, facilitating a more stable observation and examination of the lower rectal as well as intestinal regions of a patient's body.

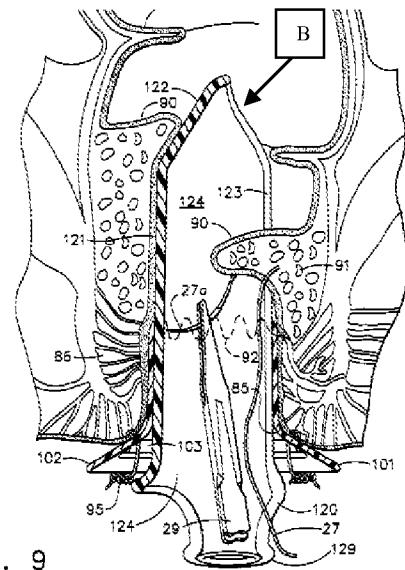
**Inserted image 1: Figs. 2A and 2B from Kaji US 6,142,931**



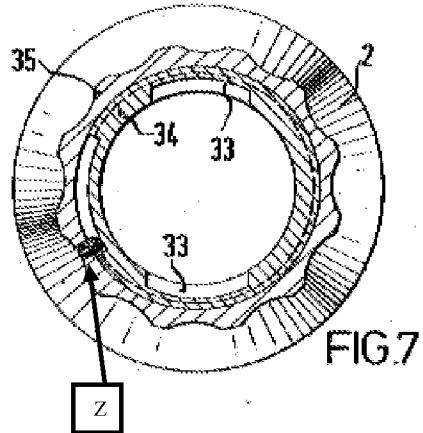
## **Inserted image 2: Fig. 1 from Longo USP 6,142,933**



**Inserted image 3: Fig. 9 from Longo USP 6,142,933**



**Inserted image 4: Fig. 7 from Boebel USP 4,538,594**



***Allowable Subject Matter***

27. Claim 48 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

28. The following is a statement of reasons for the indication of allowable subject matter: In light of the rejections presented above, the recited structure "said angular positioning element can be locked by an interaction between said peg and each of said notches" in claim 48 cannot be rendered obvious in the combination of Longo in view of Boebel nor the combination of Longo in view of Boebel in view of Golson. Although, Boebel teaches an angular positioning element that can be locked by an interaction between a peg and a notch, the combination as discussed above, would not render the required interaction between the peg recited in claim 46 and each of the notches recited in claim 39 obvious or even possible.

***Response to Amendment***

29. The amendment to claims 25, 27, 50, 52, the cancellation of claim 49, and the addition of new claims 53-56 in the response filed on December 4th, 2008 is acknowledged and has been entered.

30. Claims 25-35, 37-48, and 50-56 are currently pending in the application.

***Response to Arguments***

31. Applicant's arguments with respect to claims 25-35 and 37-52 have been considered but are moot in view of the new ground(s) of rejection.

32. However, Applicant's arguments with respect to claim 25 have been fully considered but they are not persuasive. In light of the amendment, wherein the subject matters of previous claims 36 and 49 were incorporated into claim 25, the Kaji reference still anticipates all of the limitations recited in claim 25. With respect to the window on the second hollow body, Kaji's window 32 on the second hollow body 4 is an operating window and is of constant size. That is, at no time does the size of the window 32 on the second hollow body 4 ever change.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALIREZA NIA whose telephone number is (571)270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. N./  
Examiner, Art Unit 3739  
Alireza Nia  
December 19<sup>th</sup>, 2008

/Linda C Dvorak/  
Supervisory Patent Examiner, Art Unit 3739